K102443 (1/2)

DePuy Mitek Inc. never stop moving

PRODUCT: INTRAFIX TIBIAL SHEATH
SUBMISSION DATE: AUGUST 20, 2010
SUBMISSION TYPE: SPECIAL

ATTACHMENT 1

510(k) SUMMARY - INTRAFIX TIBIAL SHEATH

OCT 20 2010

SUBMITTER'S NAME AND ADDRESS

DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

CONTACT PERSON

Deep Pal
Regulatory Affairs Specialist II
DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

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E-MAIL	dpal3@its.jnj.com
DATE PREPARED	8/25/2010

NAME OF MEDICAL DEVICE

CLASSIFICATION NAME

Fastener, Fixation, Nondegradable, Soft Tissue

COMMON/USUAL NAME

Bone Anchor

PROPRIETARY NAME

Intrafix Tibial Sheath

SUBSTANTIAL EQUIVALENCE

Intrafix Tibial Sheath is substantially equivalent to the following devices.

- Intrafix Tibial Sheath (K983560) – Modified Device
- Femoral Intrafix (K063577)

FDA PRODUCT CODE

MBI

DEVICE CLASSIFICATION

This type of **fixation sheath** was originally classified as a **Class II** medical device by the **Orthopedic Review Panel,** regulated as 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener.

K102443 (2/2)

ATTACHMENT 1

Continues...

510(k) SUMMARY - INTRAFIX TIBIAL SHEATH

DEVICE DESCRIPTION

The proposed Intrafix System consists of two components, a non-absorbable Intrafix Expansion Sheath and a non-absorbable Intrafix Expansion Screw. Also included within the system is the instrumentation to place devices and establish the tunnel. The device functions by establishing the tunnel and placing the expansion Sheath into the tibial tunnel by the use of Sheath Inserter. This is followed by screwing an Expansion Screw into the Sheath expanding the Sheath which compresses the graft against the tunnel and creating fixation.

INDICATIONS FOR USE

Intrafix Sheath is indicated for fixation of soft tissue grafts during cruciate ligament reconstruction surgeries of the knee.

TECHNOLOGICAL CHARACTERSTICS

The design specifications of the proposed Intrafix Tibial Sheath is substantially equivalent to the existing Intrafix Tibial Sheath cleared under 510(k) K983560, except that the proposed Intrafix Tibial Sheath design include the same **Sheath** material - Polypropylene *(Ethicon Prolene)* used in the Femoral Intrafix **Sheath** cleared under K063577. Technological characteristics including design, packaging and indications are the same as the predicate cleared device and use similar or identical material and packaging as the predicates.

NONCLINICAL TESTING

Verification activities, such as, Insertion Torque, Pullout Strength, Displacement Test were performed on the implant and its predicate device.

SAFETY AND PERFORMANCE

Results of performance and safety testing have demonstrated that the modified device is substantially equivalent to the predicate devices.

Based on the indications for use, technological characteristics, and comparison to predicate devices, the proposed Intrafix Tibial Sheath has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Mitek, A Johnson & Johnson Company.
% Mr. Deep Pal
Regulatory Affairs Specialist II
325 Paramount Drive
Raynham, MA 02767

OCT 20 2010

Re: K102443
Trade/Device Name: Intrafix Tibial Sheath
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 7, 2010
Received: October 12, 2010

Dear Mr. Pal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

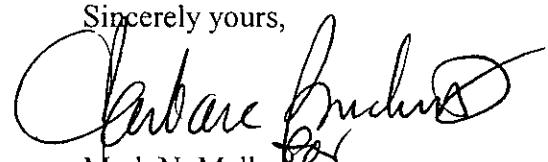
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 2

INDICATIONS FOR USE

510(k) Number (if known): K102443

OCT 2 0 2010

Device Names: Intrafix Tibial Sheath

Indications for Use: Intrafix Tibial Sheath is indicated for fixation of soft tissue grafts during cruciate ligament reconstruction surgeries of the knee.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Page 1 of 1

for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102443